Mesh in Prolapse Surgery

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Introduction

Prolapse repair with synthetic mesh has become an area of debate in the last few years. The rationale for mesh use in prolapse surgery, the surgical outcomes and its complication profile will help us to understand the concerns and controversies regarding it. The lifetime risk of undergoing surgery for prolapse by age 80 is around 11 % and reoperation rate is quoted around 29 % [1]. The recurrence risk and the need for reoperation in nearly one-third to one-fourth of patients with prolapse surgeries means there is a need for more robust techniques in prolapse repair. Our understanding of pelvic floor anatomy changed dramatically since the description of "levels of pelvic organ support" by John DeLancey [2]. In order to fully understand the dynamics of prolapse surgery, both native tissue and mesh repair, it is important to have a brief overview of the functional anatomy of the pelvic floor, which has been covered adequately in an earlier chapter of this textbook. Many of the treatments for pelvic organ prolapse (POP) offered today have been developed bearing in mind this renewed understanding of pelvic floor anatomy.

Fascial repair also known as native tissue repair has been the mainstay of surgical treatment of pelvic organ prolapse until about two decades ago. The traditional repairs for the anterior and posterior compartments are performed vaginally as these operations are inherently difficult to perform via abdominal or laparoscopic approach. Native tissue repairs traditionally address midline fascial defects, but it is usually difficult to treat paravaginal or lateral defects in the fascial hammock. These defects account for a significant proportion of cystoceles and smaller proportion of rectoceles.

Recurrence risk with prolapse repair appears to be significant in the anterior compartment compared to the apical and posterior. In a study by Weber et al. comparing three different anterior repair procedures with a 23-month follow-up, failure rate of 70 % has been reported after a "standard" anterior repair [3]. The recurrence rate in the posterior compartment after posterior colporraphy is around 12–20 % [4]. The high rate of postoperative recurrence especially in the anterior compartment means there is clearly a potential to devise a mechanism or an operation that would effectively address all "parts" of the fascial hammock. Surgery addressing both level 2 and level 1 support concurrently. Thus, the enthusiasm for mesh surgery in prolapse repair was born out of the need to provide a more strong and reliable technique.

The next step in mesh repair was the selection of an ideal mesh type for prolapse repair.

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Biological materials and absorbable synthetic materials were not the best as they were not designed to produce permanent support to the weakened tissue and the primary aim with mesh was to reduce the recurrence risk. Among the nonabsorbable synthetic meshes, the type I (Amid classification) mesh was considered better for vaginal prolapse repair [5]. The type I mesh products are macroporous (>75 μm), monofilament fibers in a woven architecture. This type of mesh has been shown to promote better integration into the host tissue through scar formation.

Mesh Repair

Mesh use in prolapse surgery can be either "augmented" mesh repair (mesh overlay) or mesh "replacement" (needle kit). The first-generation needle-driven kits like Perigee™ (American Medical Systems), (Fig. 16.1) used helical needles through the obturator foramen to place a new hammock-type polypropylene mesh. The principle was that it would effectively address multiple defects in the fascial hammock. Anterior PROLIFT™ (Johnson and Johnson, NJ) worked on a similar principle. Similar meshes were developed to address the posterior compartment and apex: Apogee ™ (American Medical system), Posterior and Total PROLIFT™ (Johnson and Johnson, NJ).

In response to safety concerns raised by the US Food and Drug Administration (FDA) advisory statement [6, 7], first-generation mesh kits that involved relatively blind needle passes, resulting in uncommon but serious neurovascular complications, were modified in search of safer alternatives. The second-generation mesh kits use a single vaginal incision for both dissection and introducing the mesh device. These mesh kits use trocar-less delivery systems and lighter meshes and include the Elevate™ system (American Medical System) (Fig. 16.2) and Pinnacle™ (Boston Scientific). These mesh devices obviate the need to use blind needle pass and thereby reduce complication rates related to insertion.

Fig. 16.1 Perigee system

Principles in Mesh Repair

The first principle in mesh repair is the recognition that in most cases, POP can be treated successfully without mesh, thus avoiding the risk of mesh-related complications. Mesh surgery is chosen only after weighing the risks and benefits of surgery with mesh versus all surgical and nonsurgical alternatives [6–8]. The specific technique with each of the mesh kits is beyond the scope of this chapter, but the general guiding principles are discussed below.

Appropriate positioning of the patient is important to have adequate access for needle insertions and movement of trocars. It is incumbent on the surgeon to ensure correct patient positioning. There are no requirements for any special instruments and it is preferable to keep instrumentation simple and to bare minimum. Usually, a Scott retractor or the Lone Star retractor is helpful.

With trocar-based kits, it is good practice to mark the surface anatomy of the obturator foramen, adductor longus tendon, pubic tubercle, ischiopubic

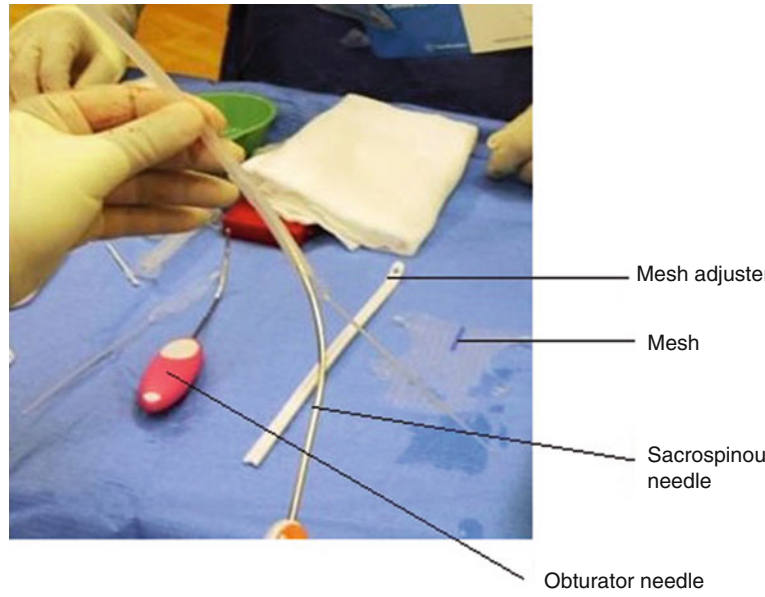

Fig. 16.2 Elevate system

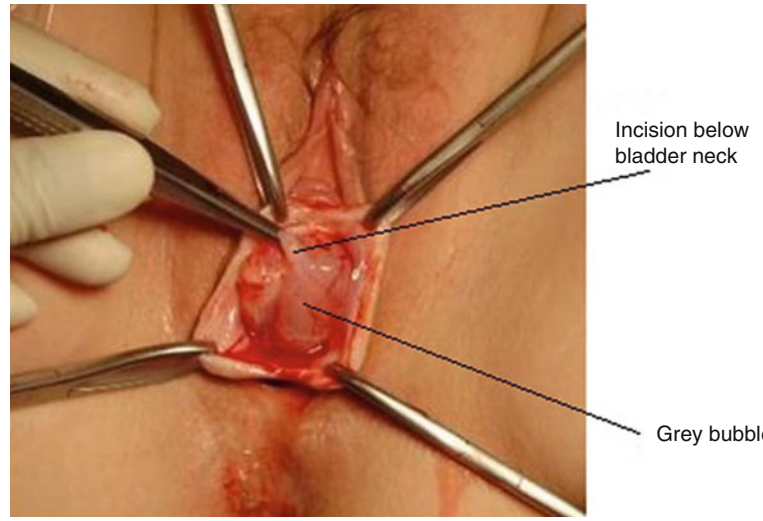

Fig. 16.3 Hydro-dissection and site of incision

ramus and ischial tuberosities before the incision. Additionally, it is useful to mark the bladder neck. Incising below the bladder neck potentially reduces the incidence of postoperative voiding dysfunction. In addition, a gynecologic pelvimetry helps to assess the subpubic angle for adequacy of access and the accessibility of the ischial spines and the sacrospinous ligaments. These are the important landmarks that need to be identified prior to any kind of pelvic floor reconstruction.

Procedure usually starts with hydrodissection with local anesthetic (Marcaine 0.5 %) mixed with diluted epinephrine (1 in 200,000). This helps in developing the natural avascular tissue plane and facilitates full-thickness vaginal dissection. Fluid in the space between the viscus and vaginal wall helps to define the correct plane of dissection (Fig. 16.3). A combination of sharp and blunt dissection carried out in this plane ensures the fascia is left attached to the vaginal

wall rather than to the viscus [9]. This ensures that the mesh lies directly in apposition with the prolapsing organ, reducing the chance of vaginal mesh extrusion.

Anchorage of the mesh to a strong pelvic floor support is pivotal to the success of mesh replacement surgery. The sacrospinous ligament fulfills the role of an "anchor," being relatively avascular, sturdy, with a fixed anatomical location and a well-circumscribed boundary, identifiable even in obese women. The sacrospinous ligament is approached anteriorly in mesh kits and this requires some degree of relearning and is a key skill in mesh repair [10]. To ensure a "four-point anchorage" in the anterior compartment, the needle is inserted through the obturator internus muscles and sacrospinous ligaments on either side, essentially mimicking the original "arcus-to-arcus" support of fascial bladder hammock. Intraoperative cystourethroscopy should be performed as a part of the standard operating protocol to detect inadvertent needle injury or mesh placement.

In posterior mesh placement, needle is inserted via incisions posterior to the anus, passed through ischiorectal fossa and directed towards the ischial spine to be anchored to the sacrospinous ligament complex. Rectal examination is done to rule out rectal injury, following trocar insertion and repeated at the end of the surgery.

It is recommended the mesh is trimmed to the size of the prolapse (Fig. 16.4) and placed in a "tension-free" manner. This reduces the risk of pain-related complications with mesh contracture. There is no need to excise vaginal skin prior to vaginal closure in mesh surgery. Minor trimming for purposes of aligning the edges is acceptable. A two-layered vaginal closure can make vaginal mesh exposure less likely and reduce dead space preventing hematomas. (Rane A., personal communication, 2010).

At the end of the mesh repair, there may be considerable residual laxity of the vaginal skin unlike in native tissue repairs. This in fact denotes appropriate mesh tensioning [9, 11, 12]. Mesh surgery factors in the concept of "vaginal remodeling" that allows surrounding tissues to restructure in much the same way as the vagina involutes following vaginal birth [11].

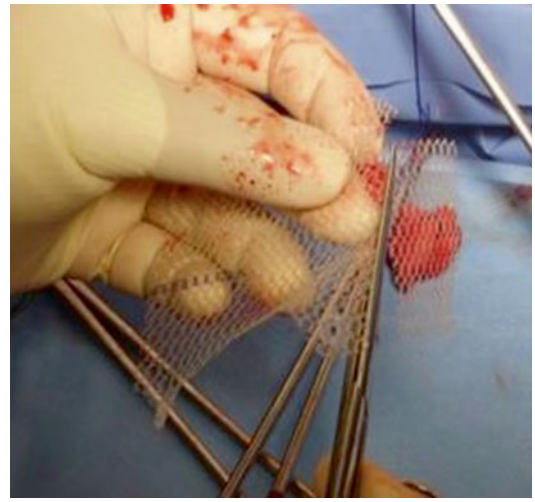

Fig. 16.4 Mesh trimmed to correct "dose"

The major issue with mesh repair is its use without adequate training. Proper training in the use of mesh devices is ideally a three-staged procedure: didactic training and cadaveric workshops, followed by preceptor training at the trainer's operating facility, and finally proctoring at the trainee's own hospital. Reference to the local college/Urogynecological society guidelines will ensure ongoing training, quality control, audit, and peer review. It is also important that mesh surgery be performed as per protocol established by the manufacturer, as any deviations from the accepted technique can cause complications and is medicolegally indefensible.

Surgical Outcomes

Several initial prospective and retrospective cohort studies using mesh kits, showed good anatomical success rates in the range of 80–100 % with follow-up over 3–24 months [13–17]. Studies with medium- and long-term follow-up and randomized controlled trials (RCT) comparing mesh versus fascial repair, showed variable results. In an one year RCT, comparing objective outcomes of mesh versus fascial repair of all compartments, there was an overall recurrence of 63 % in mesh compared to 70 % with no mesh. Most recurrences occurred in the anterior compartment - 46 % in mesh and 60 %

with native tissue [18]. In a RCT comparing anterior colporraphy with mesh, objective assessment at the end of a year showed a success rate of 61 % with mesh and 35 % with colporraphy [19]. Other RCTs comparing the mesh with standard colporraphy have shown failure rates in the range of 9–28 % with mesh [20, 21]. In one long-term outcome analysis of vaginal mesh with native tissue repair in the anterior compartment, the 5-year cumulative risk of any repeat surgery was significantly higher for vaginal mesh, 15.2 % compared to 9.8 %, but risk of surgery for recurrent prolapse was similar [22]. In the posterior compartment, fascial repairs have been shown to give excellent results and there is no evidence to support the use of mesh in posterior repair [23].

The secondary outcomes of cohort studies and RCTs started to highlight the complications rates with mesh. In the RCT by Sokol et al., mesh exposure was reported in 15 % and no statistically significant difference between mesh and native tissue with respect to new-onset dyspareunia [18]. In the study by Altman, the rates of bladder perforation and intraoperative bleed were higher in the mesh group, with mesh exposure rate of 3.2 % [19]. It was the complication profile with mesh repair, lack of evidence for optimal management of these complications and long-term sequelae related to mesh complications that constrained its use. In view of the increasing concerns about mesh-related complications, the US FDA issued statements related to mesh use in prolapse surgery [6, 7].

Complications of Mesh Surgery

Intraoperative

Cystotomy and Urethral Injury

If cystotomy occurs during dissection and is central and accessible, repair of it does not pose a problem. A single- or two-layered closure with 2/0 polyglactin should suffice and a layer of fascia could be interposed over the cystotomy to bolster the repair. It would be usual to continue with the dissection; however, opinion is divided on whether it would be safe to use mesh after a cystotomy. Some surgeons argue that a "clean" midline cystotomy, if adequately repaired, does not contraindicate mesh placement [24]. Most surgeons however would defer mesh in this scenario. More commonly cystotomies occur in the lateral "tunnels" while accessing the sacrospinous ligaments and lateral pelvic wall. Risk is increased in patients with previous surgery and almost always due to improper surgical techniques. These cystotomies are difficult to repair, and the consensus in such cases would be to avoid using mesh and resort to a fascial repair instead. Urethral trauma by needles may occur with the upper needle passes into the obturator foramen with mesh kits. Performing an intraoperative cystourethroscopy is the only reliable method of detecting this complication.

Rectal Injury

If rectal/anal injury was encountered during dissection, standard practice would dictate repair of the laceration and abandonment of mesh repair. A standard fascial repair should be considered in these patients. Rectal injury if unrecognized can lead to rectovaginal fistula.

Fornix Tear

Forniceal puncture is not unusual in women with deep lateral fornices and results during the passage of the anchors into the obturator internus muscle. Creating an adequate subcutaneous tunnel along the length of the fornix, until the ischiopubic ramus reduces this risk. The technique of directing the needle posteriorly along the length of the tunnel before changing direction under the ramus also helps. If fornix tear is identified after the passage of the anchor/mesh, it is reasonable to undermine the vaginal skin at the site of puncture and close vaginal skin over the mesh.

Bleeding

Brisk bleeding can be encountered during dissection, after mesh insertion or while deploying the anchor. Sustained pressure with a pack and gauze usually suffices, as it is usually a venous bleed. In rare occasions, using hemostatic agent like Floseal™ (Baxter, IL) may be needed. Retroperitoneal hemorrhages with large hema-

toma have been reported with transvaginal mesh surgeries [25]. If a major vessel laceration is suspected, help from a vascular surgeon or an interventional radiologist may be indicated. Heavy bleeding from the iliac vessels can be life-threatening, necessitating a laparotomy and surgical vascular control.

Late Complications

Vaginal Mesh Exposure

Vaginal mesh exposure occurs in about 13–15 % of cases [18, 24]. The mean timing of exposure is around 234 days (range of 45–1040 days) [26]. Mesh exposure risk is not limited to vaginal mesh placement and has been reported with mesh use in abdominal sacrocolpopexy (ASC) as well. With anterior mesh, the risk of exposure is 9 %, with posterior mesh 8 % and with ASC risk is around 3 % [26]. The risk of vaginal mesh exposure is higher if the mesh is sutured vaginally during sacrocolpopexy [24]. Vaginal mesh exposure is possibly a healing abnormality when it occurs early, along the suture line and with no signs of infection. It can also be detected in the lateral vaginal wall or fornices. In a proportion of patients where mesh exposure is small (<0.5 cm) and asymptomatic, it can be managed with vaginal estrogen with or without mesh excision as an outpatient procedure. The vast majority, however, need to be reoperated with excision of mesh and fascial repair over the defect. Reoperation rate for mesh exposure is quoted between 8 and 36 % [24].

Visceral Mesh Extrusion

Bladder, urethral and rectal mesh extrusions have been reported after both vaginal mesh surgery and ASC. Bladder extrusion can present with hematuria, recurrent UTI, pain or fistula. Patients who have constant urinary or fecal incontinence immediately after surgery should be evaluated for vesicovaginal or rectovaginal fistula. Treatment involves removal of the entire mesh from the viscus, repair of the visceral defect and closure of vaginal defect. This can be done vaginally, but more often an open abdominal approach is needed. Laparoscopic and cystoscopic transurethral removals have been reported and the important principle is to remove the mesh completely. Urethral erosions are managed with urethrolysis, graft explanation and multilayer closure with Mauritius flap reinforcement.

Pain

The most troublesome and concerning complication of mesh is the pain resulting from contraction and/or hardening of the mesh, leading to dyspareunia and chronic pelvic pain. Feiner et al. defined mesh contraction as an adverse outcome following polypropylene mesh repair where patients experience vaginal pain with movement and dyspareunia [27]. Contraction typically occurs along the fixation arms of the mesh and rarely does the entire implanted mesh contracts. On examination, patient can have localized areas of prominent, tense and tender mesh under the vaginal epithelium. The reported rate of polypropylene mesh-related pain, ranges between 4 and 11 % according to the definition used [24].

Management usually involves meticulous history taking, mapping of the pain with accurate charting of the trigger points and extensive counseling. In-office trigger-point injection of bupivacaine with triamcinolone is useful to accurately identify the location of pain that is causing dyspareunia. After injection, the patient is asked to return home and resume sexual intercourse. If dyspareunia diminishes, surgical removal of the involved mesh segment is likely to ameliorate symptoms. If dyspareunia persists after injection, the problem may not be related to the mesh. This can be helpful in counseling the patient prior to mesh excision.

Mesh contraction should be managed by a surgeon who is experienced in extensive deep pelvic dissection, which is necessary to remove the mesh arms. Complete excision of mesh should be attempted only by experienced surgeons. The most troublesome segments can be excised with full-thickness vaginal dissection. Symptomatic relief is noted in over 90 % of patients, but sadly a few patients may never be cured completely [27]. Therefore, it is essential that women are

adequately counseled before primary surgery and particularly prior to reoperation to treat complications.

Diffuse vaginal pain after mesh implantation is unusual and in these patients, the report of pain has been preceded by an underlying pelvic pain syndrome. Management of such pain is controversial and many patients may not be cured even after the entire graft is removed. An existing pelvic pain syndrome should ideally be elicited in patients where mesh repair is considered.

The US FDA report (2011) stated that vaginal pain and dyspareunia were the most common adverse events reported [7]. Tijdink et al.'s report on surgical management of mesh complications stated that the most common reason for reoperation following transvaginal mesh was vaginal pain and dyspareunia (77 %) [28]. This is in contrast to the common perception that vaginal extrusion is the most common complication.

Infection

The exact rate of infection with vaginal mesh is unknown. With the type 1(Amid classification) mesh, the risk of infection is rare but has been reported. Untreated preoperative bacterial vaginitis is suspected to be an underlying cause. Typically, these patients complain of vaginal discharge and bleeding and can present with vaginal exposure of the mesh. Antimicrobial therapy should cover gram-positive, gram-negative, and anaerobic bacteria and the infected exposed mesh should be removed. Complications such as abscess, cellulitis and spondylodiscitis can occur with mesh repair and are quoted to be <1 % [24].

In order to achieve some uniformity in reporting mesh-related complications and also to simplify the auditing and reporting process for the same, a code-based classification has been proposed jointly by the International Urogynecological Society (IUGA) and the International Continence Society (ICS). This classifies mesh complications based on the category (C), time (T), and site (S) of complication and referred to as the CTS classification [29]. It is suggested that while reporting mesh complications, the CTS terminology and classification is used.

Factors Influencing Mesh Complications

Obesity (BMI >30) and smoking are independent risk factors for mesh exposure [30]. Sexual activity has also been reported to be a risk factor for vaginal mesh exposure. However, this could simply reflect that those who are sexually active are more likely to identify a mesh exposure. The association of concomitant hysterectomy with risk of mesh exposure has been an area of controversy with some studies suggesting increased risk, while others did not find any difference. A meta-analysis demonstrates that the addition of hysterectomy to a transvaginal mesh surgery significantly increases the risk of mesh exposure from 7.3 % without hysterectomy to 19.2 % with hysterectomy [24].

Prevention of Complications

Transvaginal mesh implants should be used with caution in certain group of patients (Table 16.1). In addition, it is important for surgeon to understand the dynamics of the mesh kit being used. Owing to the wide variety of devices available, it is important to appreciate that every "needle" in every "kit" is different: helical needles, open curve needles, self-retrieving needles and needles

Table 16.1 Patients where mesh should be used with caution in prolapse surgery

1. Primary prolapse cases
2. Patients younger than 50
3. Lesser grades of prolapse (POP-Q ordinal grade 2 or less)
4. Posterior compartment prolapse without significant apical descent
5. Patients with chronic pelvic pain
6. Postmenopausal patients who are unable to use vaginal estrogen therapy for any reason
7. Patients with previous irradiation
8. Poorly controlled diabetics
9. Patients on high-dose immunosuppressant and corticosteroids
10. Patients who do not want "foreign material" used in their repairs

with inner and outer sheaths. Knowledge of surgical anatomy, especially an appreciation of the course of the needles in the sagittal, coronal and axial planes of the pelvis, is crucial to the surgical safety. Complications occur when the surgeon fails to appreciate the counterintuitive movement of the needle; for example, with helical obturator needles, the handle needs to be pressed firmly in contact with the patient. If the handle is raised, the tip of the needle which is deep inside the pelvis moves away from the obturator foramen and has the potential to injure vessels and nerves in the lateral pelvic wall. Therefore, appreciating directional reversal of the needle tips with respect to the handles and understanding the spatial relationship of the structures and the needles within the pelvis, in a three dimensional view are critical [9, 31]. Widespread use of these devices without proper training and in the absence of robust trials to address the pros and cons of this new technology has resulted in uncommon yet serious complications [32–35]. The proliferation of different types of synthetic and biologic meshes without comprehending their individual biodynamics can lead to delayed complications [6–8, 36–40]. A "three-step training program" for the nouveau surgeon referred earlier is invaluable.

Current Role of Mesh in Prolapse Surgery

Attempts have been made to analyze the current role of mesh in prolapse surgery after the US FDA safety communication report [6, 7]. Review of the various outcomes with mesh surgery and comparing it with native tissue repairs has led to certain recommendations in each compartment.

In the apical compartment, commonly performed procedures are abdominal sacrocolpopexy (ASC) or uterosacral ligament or sacrospinous ligament suspension with or without vaginal hysterectomy. Comparing the ASC by laparoscopy with vaginal mesh repair, Maher et al. showed a higher objective success rate at 2 years with laparoscopic sacrocolpopexy (77 % vs. 43 %). The reoperation rate was higher with vaginal mesh repair 22 % compared to 5 % with laparoscopic sacrocolpopexy [41]. Comparison of the traditional native tissue vaginal repair in the apical compartment with vaginal mesh repair, the recurrence of POP at operated site was 45 % in native tissue and 10 % in mesh group at the end of 12 months. However, mesh exposure was detected in 17 % [42]. In the apical compartment, ASC has superior outcomes compared to a variety of vaginal procedures including sacrospinous colpopexy, uterosacral colpopexy and transvaginal mesh, with an acceptable risk-benefit ratio [43].

In posterior compartment prolapse, midline fascial plication without levatorplasty is the recommended procedure of choice. No evidence supports site-specific repair or the use of polypropylene mesh or biological graft in posterior compartment repair [23]. Anterior compartment prolapse has the highest potential for recurrent prolapse with traditional native tissue repair [3]. The review at the fifth International Consultation of Incontinence stated that "Consistent level 1 evidence demonstrates superior subjective and objective outcomes following anterior transvaginal polypropylene mesh as compared to anterior colporrhaphy (grade A)." The conclusion based on this was that polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue repair. These benefits however, must be considered in the context of increased morbidity associated with anterior polypropylene transvaginal mesh [44]. Newer lightweight single-incision mesh kits show promise in reducing the complications profile and require further evaluation.

Conclusion

The introduction of mesh in pelvic organ prolapse surgery undoubtedly revolutionized the surgical options available for POP. Good anatomical outcomes have been demonstrated with its use especially in the anterior compartment. However, the use of mesh in pelvic reconstructive surgery is associated with a risk of specific complications. Preoperatively, patients must be informed of these risks and informed of conservative and alternative surgical techniques. Mesh has a role in

reconstructive pelvic surgery in complex cases and in those with high risk of failure. Proper patient selection, standardization of the surgical techniques and improved surgical training are of paramount importance. Postoperative evaluation should take into account not only the objective outcomes but also the functional outcomes in POP surgery.

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